X-SITE MEDICAL

CE 0044

X-PRESS™
6 French Vascular Closure System

INSTRUCTIONS FOR USE

TO ENSURE PROPER USE OF THIS DEVICE AND TO PREVENT INJURY TO PATIENTS, READ ALL INFORMATION CONTAINED IN THESE INSTRUCTIONS FOR USE.

CAUTION
Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION
The X-PRESS™ 6 French Vascular Closure System is designed to deliver polyester suture to close femoral artery punctures following diagnostic and interventional cardiac catheterization procedures. The X-PRESS System has a single suture attached to two needles.

The X-PRESS System consists of the X-PRESS device (6 French), a suture pack containing a single strand of suture attached to two needles, and a knot pusher. The X-PRESS device is composed of a sheath that is mounted to the distal end of a molded hub and an integrated needle pusher. The hub incorporates a slit that allows two needles attached to a single strand of suture to be manually and individually advanced across a tissue capture region and then back into the device. The device is withdrawn, leaving a suture loop across the arteriotomy. A clinch knot is prepared and then advanced using the knot pusher, thus tightening and securing the suture loop across the arteriotomy. Hemostasis is thus achieved through a percutaneous surgical closure of the arteriotomy following catheterization. The X-PRESS device and accessories are supplied sterile and are for single use only.

STERILE | EO

INDICATIONS FOR USE
The X-PRESS 6 French Vascular Closure System is indicated for the percutaneous delivery of suture for closing the common femoral artery access site of patients who have undergone diagnostic or interventional cardiac catheterization procedures using sheaths less than or equal to 6 French in size. The X-PRESS 6 French Vascular Closure System is intended to reduce the time to hemostasis, time to ambulation (100 feet), and time to dischargeability in patients who have undergone diagnostic or interventional cardiac catheterization procedures without complicating clinical conditions, including those patients receiving Glycoprotein IIb/IIIa inhibitors.

CONTRAINDICATIONS
None known.

WARNINGS
Do not use the X-PRESS device or accessories if the package or sterile barrier have been previously opened or damaged, or if the components appear to be damaged or defective.

Do not resterilize or reuse. Single use only.

This product is to be disposed of per standard hospital medical waste disposal methods.

The X-PRESS device should not be used in patients:
- with a common femoral artery ≤ 4 mm in diameter because the bleedback (positioning confirmation) tube may be blocked,
- with severe peripheral vascular disease because the diseased artery may prevent proper needle deployment,
- or with suspected arterial punctures below the common femoral artery bifurcation because the artery may be less than ≤ 4 mm in diameter.

(Refer to "INDIVIDUALIZATION OF TREATMENT" section

PRECAUTIONS

1. The X-PRESS System should be used only by operators trained in the use of the X-PRESS System, for example, by participation in an X-PRESS System training program or equivalent.
2. Observe sterile technique at all times when using the X-PRESS System. Employ appropriate groin management post procedure and post hospital discharge to prevent infection.
3. Use a single wall puncture technique. Do not puncture the posterior wall of the artery. Avoid side-wall punctures.
4. Do not proceed with X-PRESS deployment in potentially contaminated sites.
5. Do not advance or withdraw the X-PRESS device against resistance. Use fluoroscopy to determine the cause of resistance. If excessive resistance in advancing the X-PRESS device is encountered, withdraw the device and use conventional compression methods to achieve hemostasis. Excessive force used to advance, torque, or withdraw the X-PRESS device should be avoided as it may lead to significant arterial damage.
6. In the event that the proper procedure for placement and positioning of the X-PRESS device cannot be followed, discontinue the procedure by removing the device and use standard compression methods to achieve hemostasis.
7. In the event that hemostasis is not achieved with the use of the X-PRESS device, apply manual or mechanical compression to achieve hemostasis.

A femoral angiogram should be performed prior to X-PRESS device deployment to confirm:

- The femoral artery is ≥ 4 mm in diameter.
- There is no fluoroscopically visible calcium at the arterial access site.
- The arteriotomy is above the common femoral bifurcation.
- Absence of severe peripheral vascular disease.

INDIVIDUALIZATION OF TREATMENT

As noted in the "WARNINGS" section, the X-PRESS device should not be used in patients with severe peripheral vascular disease, which is defined as:

- Severe claudication when ambulating < 100 feet.
- Weak or absent pulses in the affected limb.
- ABI < 0.5 at rest.
- Known stenosis > 50% in the iliac or femoral artery on the affected side.
- Prior vascular bypass surgery involving the affected femoral artery.

SPECIAL PATIENT POPULATIONS

The safety and effectiveness of the X-PRESS device have not been established in the following patient populations:

- Patients younger than 18 years.
- Patients who are known to be pregnant or lactating.
- Patients who are immunocompromised.
- Patients requiring a re-puncture at a site previously punctured within 48 hours of closure.
- Patients with significant anemia (hemoglobin < 10 g/DL, Hct < 30)
- Patients who are morbidly obese (body mass index > 32).
- Patients who have undergone antegrade punctures.
- Patients with a baseline INR > 1.5 (e.g., on Coumadin therapy).
- Patients with a known bleeding disorder including thrombocytopenia (platelet count < 100,000 cells/UL), thrombasthenia, hemophilia, or von Willebrand's disease.
- Patients with puncture tract angles > 55 degrees.
- Patients with small femoral arteries (≤ 4 mm in diameter)
- Patients with puncture sites in the profunda femoris or superficial femoral arteries, or at the bifurcation of the arteries.
- Patients with common femoral artery calcium which is fluoroscopically visible.
- Patients with complications at the femoral artery access site pre-sheath removal.
- Patients in whom continued heparin or other anticoagulant therapy is planned (with the exception of Glycoprotein IIb/IIIa inhibitors) following completion of the catheterization procedure.
- Patients whose ACT is > 400 seconds immediately prior to removal of the guiding catheter.

Before considering early discharge, assess the patient for the following clinical conditions:

- Conscious sedation.
- Anticoagulation, thrombolytic, or anti-platelet therapy.
- Unstable cardiac status.
- Hematoma or bleeding at the closure site.
- Pain while walking.
- Any comorbid condition requiring observation.

ADVERSE EVENTS

Potential adverse events associated with the use of the X-PRESS device or vascular access procedures include:

- Bleeding or hematoma
- AV fistula or pseudoaneurysm
- Infection
- Needle non-deployment

Additionally, polyester surgical sutures elicit a limited acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Polyester sutures are not absorbed; nor is any significant change in tensile strength known to occur *in vivo*.

The X-PRESS Vascular Closure System was evaluated in a prospective, multi-center, randomized controlled clinical study (RACE study) involving 10 centers and 493 patients, of which 393 patients were randomized and 100 patients were non-randomized training patients.

No device-related deaths were experienced in the clinical study. One patient in the device group experienced a pseudoaneurysm that was resolved with thrombin injection. Three patients in the control group experienced a pseudoaneurysm and all three were resolved with thrombin injection. Potential complications of infection, retroperitoneal bleeding, wound dehiscence, nerve injury, vessel laceration, or vessel occlusion were not seen.

Table 1: Incidence of Complications for Total Patients

Description of Event	X-PRESS Device (N = 261)	Standard Compression (N = 132)	Difference [2] [95% C.I.]	p-value
Major Complications [1]	0.4% (1/261)	2.3% (3/132)	1.9% [-0.8%, 4.6%]	0.1122
Infection at puncture site	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Transfusion due to blood loss	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Ultrasound-guided compression	0.4% (1/261)	2.3% (3/132)	1.9% [-0.8%, 4.6%]	0.1122
Vascular repair	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Death related femoral puncture	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Minor Complications [1]	1.9% (5/261)	2.3% (3/132)	0.4% [-2.6%, 3.4%]	1.0
Retroperitoneal bleed	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Wound dehiscence	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Post discharge arterial bleed	0.0% (0/261)	0.0% (0/132)	[-,-]	1.0
Hematoma > 6 cm.	1.5% (4/261)	0.0% (1/132)	-1.5% [-3.0%,-0.0%]	0.3053
Vessel laceration	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
Nerve injury	0.0% (0/261)	0.0% (0/132)	0.0% [-,-]	1.0
AV fistula	0.4% (1/261)	0.0% (0/132)	-0.4% [-1.2%, 0.4%]	1.0
Pseudoaneurysm	0.4% (1/261)	2.3% (3/132)	1.9% [-0.8%, 4.6%]	0.1122
Deep vein thrombosis	0.4% (1/261)	0.0% (0/132)	-0.4% [-1.2%, 0.4%]	1.0
Emboli	0.4% (1/261)	0.0% (0/132)	-0.4% [-1.2%, 0.4%]	1.0
Device Malfunction [3]	3.1% (8/261)	N/A		
Any Complication	2.3% (6/261)	2.3% (3/132)		
No Major Complication	99.6% (260/261)	97.7% (129/132)		

[1] A subject is counted only once for multiple occurrences of complications.

[2] Standard Compression minus X-PRESS Device.

[3] There were a total of 8 device malfunctions. Malfunctions included 5 bent needle pushers, 2 suture breaks, and 1 failed knot advancement.

CLINICAL STUDY

RACE (Rapid Ambulation after ClosurE) Study

The X-PRESS 6 French Vascular Closure System was evaluated in a prospective, multi-center, randomized controlled clinical investigation involving 393 randomized patients and 100 non-randomized training patients at 10 centers. This clinical investigation was known as the RACE (Rapid Ambulation after ClosurE) Study. The study was designed to prospectively evaluate the safety and effectiveness of the X-PRESS Vascular Closure System in reducing time to hemostasis, time to ambulation, and time to dischargeability for patients who have undergone diagnostic and interventional cardiac catheterization using up to 6 French sheaths when compared to standard compression techniques. Of the 393 randomized patients, 261 were randomized to the X-PRESS device and 132 were randomized to standard compression. Of the patients randomized to the X-PRESS device, 172 (66%) were interventional patients and 89 (34%) were diagnostic patients. Of the patients randomized to standard compression, 88 (67%) were interventional patients and 44 (33%) were diagnostic patients. Among the interventional patients, 52% (134/260) were treated with Glycoprotein IIb/IIIa inhibitors.

The overall ACT (Activated Clotting Time) level at the time of sheath removal for the X-PRESS device group ranged between 89 to 410 seconds with an average of 226 (S.D. 74) seconds. The overall ACT level at the time of sheath removal for the standard compression group ranged from 89 to 360 seconds with an average of 170 (S.D. 51) seconds. The ACT level for diagnostic X-PRESS device patients ranged between 89 to 292 seconds with an average of 145 (S.D. 35) while the ACT level for diagnostic standard compression patients ranged between 105 to 217 seconds with an average of 141 (S.D. 27) seconds. The X-PRESS device interventional patients' ACT ranged between 131 to 410 seconds with an average of 266 (S.D. 53) seconds while the interventional standard compression patients' ACT ranged between 89 to 360 seconds with an average of 187 (S.D. 54) seconds.

Analysis of the 393 randomized patients showed significantly reduced times to hemostasis, ambulation, and dischargeability in the X-PRESS device group for both diagnostic and interventional patients compared to the standard compression group. Time to discharge was also significantly lower in the X-PRESS device diagnostic patients. There was no significant difference in the rate of major complications overall between the X-PRESS device group (0.4%) and the standard compression group (2.3%). The reductions in time to hemostasis, time to ambulation (100 feet), and time to dischargeability for X-PRESS interventional patients are unaffected by the use of Glycoprotein IIb/IIIa inhibitors.

Table 2: Effectiveness Results by Procedure Type

	Diagnostic			Interventional		
	X-PRESS Device	**Standard Compression**	**p-value**	**X-PRESS Device**	**Standard Compression**	**p-value**
	Mean (SD) n [3] Median Range	Mean (SD) n [3] Median Range		Mean (SD) n [3] Median Range	Mean (SD) n [3] Median Range	
Time to Ambulation (hours) [1]	3.0 (4.87) 84 2.2 1.5-45.7	8.5 (11.32) 42 6.2 3.1-70.2	0.0001	7.1 (7.78) 164 4.1 2.0-74.9	16.5 (7.76) 86 14.7 5.4-45.5	0.0001
Time to Hemostasis (min) [1]	11.7 (15.76) 88 9.0 1.0-140.0	54.7 (31.41) 44 49.5 11.0-180.0	0.0001	29.8 (82.86) 170 10.0 2.0-666.0	280.2 (172.63) 86 269.5 36.0-1170.0	0.0001
Time to Dischargeability (hours) [1]	3.7 (5.24) 85 2.5 1.5-45.8	9.3 (13.56) 42 6.4 3.6-70.2	0.0001	9.7 (10.69) 167 5.3 2.7-74.9	18.1 (7.82) 86 16.8 7.0-45.5	0.0001
Time to Discharge (hours) [1]	23.6 (50.46) 85 4.8 2.1-319.7	36.4 (59.46) 44 7.6 3.4-217.4	0.0164	30.5 (24.61) 167 24.2 4.9-193.3	37.3 (47.74) 85 25.3 17.1-352.8	0.06
Treatment Success (%) [2]	94.4% (84/89)	100% (44/44)	0.17	90.7% (156/172)	95.5% (84/88)	0.2233
Procedure Success (%) [2]	98.9% (88/89)	100% (44/44)	1.0	100% (172/172)	96.6% (85/88)	0.0379

[1] The comparison of the survival curves of the two treatments are evaluated by the Log-rank test.
[2] Categorical variables are evaluated by Fisher's exact test.
[3] The number of patients is not the same as the number studied due to missing patient data.

Time to ambulation is defined as the time from the removal of the guiding catheter to when the patient stands and can walk 100 feet and maintain hemostasis.

Time to hemostasis is defined as the time from guiding catheter removal to cessation of common femoral artery bleeding as determined by visual inspection.

Time to dischargeability is defined as the time from the removal of the last catheter to when the patient is ready for discharge, defined as the ability to walk 100 feet, freedom from orthostatic hypotension (stable blood pressure and heart rate after ambulating), ability to void, and a stable groin site without bleeding or expansion of prior hematoma.

Time to discharge is defined as the time from the removal of the guiding catheter to patient discharge.

Treatment success is defined as the attainment of stable hemostasis of the femoral arteriotomy site utilizing the randomized treatment only and freedom from a major complication during the follow-up period of approximately 14 days following treatment.

Procedure success is defined as achievement of hemostasis without the occurrence of major complications through the follow-up period of approximately 14 days following treatment.

Table 3: Effectiveness Results Stratified by Glycoprotein IIb/IIIa Inhibitor Therapy

	Interventional					
	X-PRESS Device With GP IIb/IIIa Inhibitor Therapy	**Standard Compression With GP IIb/IIIa Inhibitor Therapy**	**p-value**	**X-PRESS Device Without GP IIb/IIIa Inhibitor Therapy**	**Standard Compression Without GP IIb/IIIa Inhibitor Therapy**	**p-value**
	Mean (SD) n [3] Median Range	Mean (SD) n [3] Median Range		Mean (SD) n [3] Median Range	Mean (SD) n [3] Median Range	
Time to Ambulation (hours) [1]	7.2 (5.81) 83 4.2 2.2-24.9	18.9 (8.58) 45 17.6 7.3-45.5	0.000	7.1 (9.41) 81 4.1 2.0-74.9	13.8 (5.76) 41 11.7 5.4-28.8	0.000
Time to Hemostasis (min) [1]	30.4 (83.48) 86 10.0 2.0-656.0	295.7 (188.86) 46 257.0 36.0-1170.0	0.000	29.2 (82.7) 84 10.0 3.0-666.0	262.5 (152.29) 40 271.0 43.0-887.0	0.000
Time to Dischargeability (hours) [1]	9.5 (8.63) 84 5.3 3.2-48.7	19.2 (8.50) 45 17.8 7.3-45.5	0.000	10.0 (12.5) 83 5.1 2.7-74.4	16.9 (6.93) 41 16.1 7.0-40.3	0.001
Time to Discharge (hours) [1]	29.4 (18.45) 85 23.9 17.2-126.0	39.4 (43.77) 45 28.1 17.2-126.0	0.0103	31.7 (29.74) 82 24.2 4.9-193.3	34.8 (52.3) 40 23.7 17.1-352.8	0.911
Treatment Success (%) [2]	89.8% (79/88)	100% (46/46)	0.0274	91.7% (77/84)	90.5% (38/42)	1.0
Procedure Success (%) [2]	100% (88/88)	100% (46/46)	1.0	100% (84/84)	92.9% (39/42)	0.0353

[1] The comparison of the survival curves of the two treatments are evaluated by the Log-rank test.
[2] Categorical variables are evaluated by Fisher's exact test.
[3] The number of patients is not the same as the number studied due to missing patient data.

Table 4: Effectiveness Results by Post-Procedure Time Interval for Total Patients [1]

Parameter	Patient Group	Time Interval					
Percentage of Patients Ambulating Within Time Interval		*3 hr*	*6 hr*	*9 hr*	*12 hr*		
	X-PRESS (n)	28.70% (75)	72.80% (190)	81.20% (212)	85.82% (224)		
	Std Comp (n)	0.00% (0)	12.90% (17)	35.60% (47)	53.03% (70)		
Percentage of Patients Achieving Hemostasis Within Time Interval		*60 min*	*120 min*	*180 min*			
	X-PRESS (n)	94.60% (247)	95.02% (248)	96.17% (251)			
	Std Comp (n)	26.50% (35)	40.91% (54)	50.00% (66)			
Percentage of Patients Ready for Discharge Within Time Interval		*6 hr*	*12 hr*	*18 hr*	*24 hr*		
	X-PRESS (n)	66.30% (173)	79.70% (208)	85.44% (223)	91.19% (238)		
	Std Comp (n)	10.60% (14)	47.00% (62)	65.90% (87)	84.85% (112)		
Percentage of Patients Discharged Within Time Interval		*12 hr*	*24 hr*	*36 hr*	*48 hr*	*60 hr*	*72 hr*
	X-PRESS (n)	25.30% (66)	56.70% (148)	83.10% (217)	85.44% (223)	89.66% (234)	90.04% (235)
	Std Comp (n)	22.70% (30)	51.50% (68)	74.24% (98)	82.58% (109)	89.39% (118)	89.39% (118)

[1] Ns = 261 X-PRESS patients and 132 Standard Compression patients.

X-PRESS CLINICAL PROCEDURE

The medical techniques and procedures described in these instructions for use do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. These directions are not intended to obviate the need for formal training in the use of the X-PRESS device.

Supplies

(1) X-PRESS 6 French Device
(1) X-PRESS Knot Pusher
(1) .038" x 45 cm Guidewire

1. The X-PRESS 6 French device should be selected for the closure of 6 French or smaller introducer sheath access sites.
2. After carefully inspecting the packaging of the X-PRESS device and accessories for damage to the sterile barrier, remove the device from the package following standard sterile technique.

Arterial Puncture Considerations

1. Puncture the anterior wall of the common femoral artery at an angle of ≤55 degrees. Puncture tract angles greater than 55 degrees should be avoided.
2. Avoid side or posterior wall punctures.

X-PRESS Device Placement

1. After completion of the catheterization procedure, use fluoroscopy with contrast injection through the introducer sheath to verify that the access site is in the common femoral artery. Evaluate the femoral artery for size, calcification, and vascular disease.
2. While the introducer sheath remains in place, insert an .038-inch guidewire through the sheath and into the artery lumen until approximately half of the guidewire remains above the skin line.
3. Carefully withdraw and remove the introducer sheath from the artery, leaving the guidewire in place while maintaining upstream occlusive pressure at the puncture site.
4. Backload the proximal end of the guidewire into the distal end of the X-PRESS device. Advance the X-PRESS device over the guidewire until the guidewire exits through the guidewire exit port of the X-PRESS device.
5. Advance the X-PRESS device over the guidewire until the guidewire exit port is below the skin line but has not entered the artery. Withdraw and remove the guidewire.
6. Advance the X-PRESS device following the angle of the tissue tract until blood is flowing through the positioning lumen. The arched section of the device will now be across the vessel wall. To ease insertion, the device should be rotated back and forth approximately 90 degrees in either direction. If blood is not flowing from the positioning lumen, the X-PRESS device is not properly positioned and needle deployment should not be attempted. Do not advance the device against significant resistance.

NOTE: If blood is not exiting from the positioning lumen after attempts to reposition the device, remove the device and follow standard compression protocol.

Needle Deployment

1. Orient the X-PRESS device so that the needle slot is in the 12 o'clock position relative to the operator.
2. Place the needle attached to the black suture into the needle slot entry lumen. Ensure that the entire needle section is contained within the X-PRESS hub before advancing. Gently advance the needle to the distal end of the hub by pulling forward on the suture.
3. Holding the X-PRESS device in position, advance the needle attached to the black suture across the vessel wall by advancing the needle pusher until it cannot be further advanced. ADVANCE THE NEEDLE PUSHER THE ENTIRE DISTANCE IN ONE CONTINUOUS FAST MOTION. Retract the needle pusher.
4. Place the second needle attached to the white suture into the needle slot entry lumen as described in step 2.
5. Rotate the X-PRESS device 180 degrees clockwise so that the needle entry lumen is now in the 6 o'clock position. Advance the second needle attached to the white suture across the vessel wall as previously described. Limited resistance to device rotation may be felt depending on the amount of scar tissue.

WARNING: In the event that the needles fail to deploy or only partially deploy, or if significant resistance is encountered, terminate the procedure. Remove the needles by pulling suture toward the operator. If the needles cannot be removed, follow the procedure outlined in the "DEVICE REMOVAL" section below.

6. Withdraw the X-PRESS device until the arch is approximately 1 inch above skin line, then readvance the arch back to the skin line, creating slack in the suture.
7. Pull the needles from the sheath. Place the left index finger into the loop and hold the loose suture ends in the other hand, then tug gently on the loop. If the loop holds tension, remove the index finger and pull on the loose suture ends until the loop is completely advanced across the arteriotomy. Continue to step 9. If the loop does not hold tension, proceed to step 8. DO NOT PASS EITHER SUTURE END THROUGH THE LOOP, AS THIS WILL PREVENT THE KNOT FROM ADVANCING.
8. If the loop pulls out and is lost, at least one side of the vessel was not captured. The procedure may be restarted by cutting the suture and removing it completely, opening a new sterile suture pack, and continuing from step 6 under the X-PRESS device placement section.
9. Place a hemostat or similar object on the skin line in between the loose suture ends. Place the black suture above and the white suture below the hemostat.
10. Prepare a clinch knot (see "TYING THE CLINCH KNOT" section below) just above the skin line. Once the knot is tied, remove the hemostat.
11. Cut both strands of suture to remove the needles and discard. Thread the black suture through the snare on the knot pusher, then retract the snare to pull the suture through the knot pusher. The knot pusher should slide easily over the suture.
12. Saturate the suture with saline. Apply occlusive upstream pressure and completely remove the X-PRESS device.
13. Tension the black strand of suture that is through the knot pusher with one hand while applying forward pressure to the proximal end of the knot pusher with the other hand.
14. Use the suture as a rail, keeping the knot pusher coaxial to the suture. Advance the knot pusher following the same angle as the original puncture. Excessive pressure should not be used. Release occlusive pressure.
15. The slit in the knot pusher hub should be used to hold the knot pusher in place. To do this, place the black suture across the end of the pusher, gently tensioning the suture until it locks in the slit. Tug on the white suture, locking the knot in place.
16. Clip the white suture just below the skin line.
17. Leave the knot pusher in place for approximately 10 minutes.
18. Clip the black suture just below the skin line utilizing sterile technique. Remove the knot pusher. If there is oozing, apply gentle pressure over the puncture site.

TYING THE CLINCH KNOT

1. Bring the black suture end above (away from the operator) and the white suture below the hemostat or similar object.
2. Hold light tension on the black suture. Make three turns around the black marked suture with the white suture.
3. Pass the end of the white suture through the loop just above the hemostat or similar object, then pass the white suture back though the large loop which is formed during step 2. Gently tug on the white suture to remove slack from the knot. Do not tighten the knot.

DEVICE REMOVAL

The following describes the recommended technique for removing the device from the artery when the position of the needles is uncertain or significant resistance is felt:

1. Use fluoroscopy to determine the position of the needles.
2 If the needles are not engaging the vessel wall, retract the device until the arch section is 1 inch above the skin line. Proceed to step 3.
2A. If the needles are engaging the vessel wall, place the device in the original 12 o'clock position, and pull on the black suture until the needle is outside the patient. Rotate the device to the 6 o'clock position, and pull on the white suture until the needle is outside the patient.
3. Confirm that both needles are outside of the patient. Cut the needles from the suture. Discard the needles. Pull on one of the suture ends until the suture is completely removed from the patient.
4. The device may be removed completely. If the device is removed and the closure procedure is abandoned, utilize standard compression techniques to achieve hemostasis.

POST PROCEDURE PATIENT MANAGEMENT

1. Assess and note peripheral circulation status.
2. Observe that the sutured site is dry when pressure is released.
3. Assess and treat the insertion site per standard treatment protocol.

Product Information Disclosure

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